

REMARKS

Claim 55 has been cancelled without prejudice.

Claim 49 has been amended to specify a method of reconstructing a joint using a reconstructive structure comprising “4 to about 200 layers of submucosa tissue.” Support for the claim amendments can be found in the Figures, particularly Figs. 4, 5, and 11-13 (which show constructs of 4, 5, 6, 8, and 10 layers) and on page 12, lines 6-8 of the captioned application. Each of the earlier applications related to the captioned application, including U.S. Application Serial No. 08/628,773 (hereinafter the ‘773 application), filed April 5, 1996, has the same support for claims specifying the use of graft constructs with “4 to about 200 layers of submucosa tissue” (see Figs. 4, 5, and 11-13 and page 9, lines 26-28 of the ‘773 application).

In an Advisory Action mailed on April 2, 2003, the Examiner indicated that the amendments made to the claims in Applicants’ response, filed on March 18, 2003, would not be entered, in part, because the phrase “about 4 to about 200 layers of submucosa tissue” (see the amendments to claim 49 in the March 18 response) may constitute new matter. Claim 49, as amended herein, specifies the use of a graft construct with “4 to about 200 layers of submucosa tissue.” Support for the word “about” in reference to 200 layers of submucosa tissue is found in each of the earlier applications related to the captioned application, including the grandparent ‘773 application, and is also found in the captioned application. For example, on page 9, lines 26-28 of the ‘773 application it is stated that “[t]he number of layers may vary between 50, for example, to *about* 200 layers” in reference to an exemplary embodiment of the graft constructs that can be used in accordance with the invention. Accordingly, the word “about” in reference to 200 layers of submucosa tissue does not constitute new matter.

The Examiner rejected, in a Final Official Action mailed on December 18, 2002, claims 49-54 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,782,915 (hereinafter the '915 patent) in view of U.S. Patent No. 5,968,096 (hereinafter the '096 patent). The Examiner contended, in the December 18 Official Action, that the '096 patent discloses removing the entire joint down to the cancellous bleeding bone, but fails to disclose the submucosa graft of 1 to 12 mm thick as claimed, and that the '915 patent teaches an 8-layer submucosa graft for use in tissue repair. The claims as amended herein clearly have the benefit of the April 5, 1996 filing date of the grandparent '773 application. Accordingly, the cited '915 patent having that same filing date (*i.e.*, April 5, 1996) is not prior art against the present claims as amended.

The captioned application is a division of U.S. Patent Application Serial No. 08/913,771, filed on December 17, 1997, which is a continuation-in-part of U.S. Patent Application Serial No. 08/628,773 (the '773 application), filed on April 5, 1996. Support for the amendment to claim 49 to specify a method of reconstructing a joint using a graft construct comprising "4 to about 200 layers of submucosa tissue" is found in the early '773 application (*i.e.*, the grandparent application). Figs. 4, 5, and 11-13 of the '773 application depict graft constructs with 4, 5, 10, 8, and 6 layers, respectively. Furthermore, on page 9, lines 26-28 of the specification of the '773 application it is stated that "[t]he number of layers may vary between 50, *for example*, to about 200 layers." The collective teachings of the application based on both the graft constructs illustrated in the drawings and those exemplified in the text of the specification make it clear that the range of layers in the graft constructs can be as few as 4 layers (see Fig. 4) to about 200 layers. This description is not only in the captioned application but it is in each of the earlier applications related to the captioned application, including the grandparent '773 application, filed on April 5, 1996.

Therefore, amended claim 49 specifying a method for reconstructing a joint using a graft construct comprising "4 to about 200 layers" of submucosa tissue, is entitled to an effective filing date of April 5, 1996 (*i.e.*, the filing date of the '773 application). The application that issued as the cited '915 patent was filed on April 5, 1996, the same date as that to which amended claim 49 is entitled. Accordingly, the cited '915 patent is not prior art to the captioned application.

The Examiner also rejected, in the December 18 Official Action, claims 49-53 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,881,773 (hereinafter the '773 patent) in view of U.S. Patent No. 5,281,422. As discussed above, the captioned application claims priority to the '773 application, filed on April 5, 1996, and the amended claims are entitled to that early effective date. The filing date of the application that issued as the cited '773 patent was September 13, 1996, after the effective date of the amended claims. Thus, the '773 patent is not properly cited as prior art against the amended claims of the captioned application.

The Examiner indicates in the April 2 Advisory Action that "it is not clear that the range of 4 to 200 layers absent the "about" language has original support" in the grandparent '773 application. However, as discussed above, the '773 application clearly describes graft constructs with 4 to 200 layers of submucosa tissue for use in reconstructing a joint. Figs. 4, 5, and 11-13 of the '773 application depict graft constructs with 4, 5, 10, 8, and 6 layers, respectively. Furthermore, on page 9, lines 26-28 of the specification of the '773 application it is stated that "[t]he number of layers may vary between 50, *for example*, to about 200 layers." Thus, the '773 application describes graft constructs with 4 to about 200 layers by illustration in the drawings and by exemplification in the text of the '773 application, making it clear that the range of layers in the graft constructs for use in accordance with the invention can be as few as 4 layers (see Fig. 4) to about 200 layers.

In this regard, MPEP § 2163.05 is directed to the written description requirement under 35 U.S.C. § 112, ¶ 1. MPEP § 2163.05, part III. is entitled “Range Limitations” and reads in its entirety as follows:

With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of “25%-60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however a limitation to “between 35% and 60%” did meet the description requirement.

Thus, a claimed range meets the § 112, ¶ 1 written description requirement under MPEP § 2163.05 if one skilled in the art would consider that the range is “inherently supported by the discussion in the original disclosure.” Furthermore, as the court concluded in *In re Wertheim*, exemplary embodiments can constitute a description of the limits of a claimed range (*i.e.*, an exemplary embodiment of “36%” constituted a description under 35 U.S.C. § 112, ¶ 1 of the lower limit of the claimed range of “between 35% and 60%”).

The range specified in amended claim 49 of “4 to about 200 layers” of submucosa tissue is described in exemplary embodiments in the drawings of the ‘773 application which show graft constructs with as few as 4 layers (see Fig. 4 of the ‘773 application), and in an exemplary embodiment on page 9, lines 26-28 of the specification of the ‘773 application where it is stated that “[t]he number of layers may vary between 50, *for example*, to about 200 layers.” Therefore, graft constructs with as few as 4 to about 200 layers are described in the grandparent ‘773 application. Thus, as required by MPEP § 2163.05, the claimed range of “4 to about 200 layers” of submucosa tissue is “inherently

supported by the discussion in the original disclosure” because graft constructs of the claimed range are clearly exemplified in the drawings and in the text of the ‘773 application.

Furthermore, as stated in MPEP § 2163.02, “[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.” Rather MPEP § 2163.02 states that “[t]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.”” *Ralston Purina Co. v. Far-Mar-Co., Inc.* 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F. 2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). As required by MPEP § 2163.02 and by 35 U.S.C. § 112, ¶ 1, the disclosure of the ‘773 application conveys to the skilled artisan that the Applicants had possession of the method of claim 49 using graft constructs of “4 to about 200 layers” of submucosa tissue because graft constructs with those numbers of layers are clearly described in the drawings and in the text of the ‘773 application.

CONCLUSION

The claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,



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